

REMARKS

The Examiner makes the following rejections:

- A. Claims 50, 99-101, 103-105, 108, 119 and 121 are rejected under section 112 as allegedly lacking written description.
- B. Claims 50, 99, 100, and 108 are rejected as allegedly obvious under section 103(a) on the basis of Walt, in view of Felder, Chang, or Ravkin, when taken with Peters.
- C. Claims 50, 99, 100, and 108 are rejected as allegedly obvious under section 103(a) on the basis of Walt, in view of Felder, Chang, or Ravkin, when taken with Kaetsu.
- D. Claims 50, 76, 99-100, 108-109, 111, 113, 119 and 120 are rejected as allegedly obvious under section 103(a) on the basis of Walt, in view of Felder, Chang, or Ravkin, when taken with Pope, Dakss and Peters.
- E. Claims 103 is rejected as allegedly obvious under section 103(a) on the basis of Walt, in view of Felder, Chang, or Ravkin, when taken with Pope, Dakss, Peters and Wang.
- F. Claims 50, 76, 99-101, 103-105, 108-111, 113-115, 119 and 120 are rejected as allegedly obvious under section 103(a) on the basis of Walt, in view of Felder, Chang, or Ravkin, when taken with Pope, Dakss and Kaetsu.
- G. Claims 103 is rejected as allegedly obvious under section 103(a) on the basis of Walt, in view of Felder, Chang, or Ravkin, when taken with Pope, Dakss, Kaetsu and Wang.

Applicants traverse and offer the following response.

A. There Is Written Description For The Claims

Claims 50, 99-101, 103-105, 108, 119 and 121 are rejected under section 112 as allegedly lacking written description. Applicants disagree. The specification teaches broadly a method for the detection of analytes wherein the sensing elements are oriented

randomly:

[0003]¹ The present invention relates to a method and device for the detection of analytes in a fluid. More particularly, the invention relates to the development of a sensor array system capable of discriminating mixtures of analytes in a fluid.

[0016] The sensing elements may include a receptor molecule coupled to a polymeric material. The receptors may interact with one or more analytes.

[0055] In one embodiment, the liquid composition used to form the supporting member has a density that is less than the density of the sensing elements. When disposed in the liquid composition, the sensing elements will sink to the bottom of the composition. Subsequent curing of the composition will produce a sensor that includes sensing elements disposed at the bottom of the sensor array. *Alternatively, the composition may have a density that is greater than the density of the sensing elements. In this situation the sensing elements may float to the surface of the composition. Subsequent curing of the composition will produce a sensor with sensing elements disposed at the top surface of the supporting member.*

[0056] The orientation of the sensing elements in the supporting member *may be random* or ordered.

Without waiving this argument or acquiescing to the Examiner's rejection, but to further the prosecution, Claim 50 has been amended to specify (for a particular embodiment) that the sensing elements are randomly oriented on a supporting member. The Examiner acknowledges (at page 2) that random placement on a support structure is supported in the disclosure. Applicants hereby reserve the right to prosecute the unamended (or similar) claims in the future, as well as pursue other embodiments.

¹ Reference is made to the paragraphs of the published application available on PAIR.

B-D, F. Claim 50 Is Not Obvious

There are two independent claims pending, i.e. Claim 50 and Claim 76, from which all other claims depend. The Examiner has made four separate obviousness rejections that involve Claim 50 (see B, C, D and F, above). Applicants cannot agree. Claim 50, as noted above, has been amended (for other reasons). All of the method steps are not taught in the cited art.

1. Claim 50 Requires Two Polymerization Steps

Claim 50 was amended (as described above). Claim 50, as amended, requires two polymerization steps. First, the sensing elements (comprising receptors for the analytes) are made from polymeric material. Second, these sensing elements are themselves embedded in polymeric material. Claim 50 specifies how this second step is done, requiring that the polymeric sensing elements be added randomly to a solution that is later cured. Still further, Claim 50 requires that the densities be different such that the sensing elements will float to the surface (so that subsequent polymerization “will produce a sensor with sensing elements disposed at the top surface of the supporting member.”) (see quote from the specification set forth above). It is respectfully submitted that the cited references, whether examined individually or collectively,² do NOT teach this combination of polymerization steps.

2. Peters Does Not Teach All Of The Steps

The Examiner cites Peters ('669) for the proposition that “it is conventional in the art to encapsulate receptor molecules within the pores of porous polymer bodies.” (see Office Action, page 5). First, Applicants must point out that a word search of the '669 published patent for “encapsulate” does not reveal the term. Second, the '669 patent merely teaches coating a porous solid surface (that has no ligands) with a polymer (that has ligands):

A solid phase binding member for an analyte in a test sample according to the present invention satisfies this need. The binding member which I prepared

² Applicants have argued and continue to believe that the combination of the cited art is improper and unjustified, since some of the art is non-analogous and/or teaches in the opposite direction. Without waiving this argument, Applicants point out here that – even if combined – the cited art does not teach all of the elements of the claims.

comprises:

- (1) a solid support having micropores;
- (2) a polymer reversibly water-soluble before its application to the solid support, the polymer being in its solid phase and impregnating at least a portion of the micropores of the solid support; and
- (3) a ligand covalently attached to the polymer, the ligand being capable of interacting specifically, directly or indirectly, with the analyte.

(see the Summary of the ‘669 patent). By contrast, Claim 50 requires that a polymeric sensing element comprising a ligand be placed in a polymeric solution (that does not have ligands) that is later cured. As such, all of the elements of Claim 50 are not taught by Peters (‘669).

3. Kaetsu Does Not Teach All Of The Steps

Kaetsu et al. (‘066) is cited by the Examiner for the proposition that “it is known in the art to form porous polymer particles that include biological active materials . . .” (Office Action, page 9). However, Kaetsu (like Peters) only teaches a single polymerization to create a porous polymer containing biologically active molecules:

“Upon completion of the polymerization, the polymer composition containing the enzyme or cells has already become porous. Therefore, this invention does not require the steps of washing, purifying, drying, grinding, etc. The enzyme or cells-polymer composition incorporating the enzyme or cells obtained by polymerizing the monomer in the present invention *is usable in the enzyme reaction, as it is.*”

(see the Detailed Description section of the ‘066 patent). As such, all of the elements of Claim 50 are not taught by Kaetsu (‘066).

4. Walt Does Not Teach All Of The Steps

The Examiner admits that Walt does not teach all of the steps of Claim 50. Specifically, the Examiner acknowledges “the reference does not specifically disclose that the receptors are at least partially encapsulated . . .” (Office Action, p. 5 and the

sentence bridging pages 8 and 9, and again on page 13). Thus, even the first polymerization step of Claim 50 is not taught by Walt.

5. Dakss And Pope Fail To Teach All Of The Steps

Dakss and Pope appear to be cited by the Examiner only to show that light-cured adhesives are known. (Office Action, p.12). These references do not teach placing polymeric material in another polymeric material, let alone with densities such that one gets embedding at the surface (as required by amended Claim 50).

6. Wang Does Not Teach All Of The Steps

The Examiner appears to cite Wang merely for an alleged description of a “square.” (Office Action, p. 15). The Examiner does not assert (and Applicants do not find) any teaching in Wang relevant to the two polymerization steps required in Claim 50.

7. Felder, Chang and Ravkin Do Not Teach All Of The Steps

The Examiner cites Felder, Chang and Ravkin for the proposition that “it is known in the art to provide analyte detection beads . . . of different size or shape.” (Office Action, p. 11). The Examiner does not assert (and Applicants do not find) any teaching in these three references relevant to the two polymerization steps required in Claim 50.

8. All The References Have Been Addressed

It is respectfully submitted that the Examiner continues to employ the *In re Keller* and *In re Merck* cases improperly. As previously pointed out, those cases involve situations where all of the references were not addressed. As shown above, Applicants have examined ALL of the references and addressed each in turn. It is respectfully submitted that the cited references, whether examined individually *or collectively*, do NOT teach the combination of polymerization steps and conditions set forth in Claim 50. As such, the obviousness rejection must be withdrawn.

D and F. Claim 76 Is Not Obvious

As noted above, the other independent claim is Claim 76. Claim 76 also requires that the sensing elements be embedded in another polymer. Furthermore, Claim 76 requires that *each sensing element have portions of different shape*. It is respectfully

submitted that the cited references, whether examined individually or collectively, do NOT teach these features of Claim 76.

1. Walt Does Not Teach A Sensor Having First And Second Portions of Different Shape

Claim 76 specifies “wherein the shape of the first portion of the sensing elements is different from the shape of the second portion of the sensing elements.” Walt does not teach anything relevant in this regard. Indeed, the Examiner appears to admit this, but points to Felder, Chang and Ravkin as allegedly teaching this limitation in Claim 76:

“In this case, it is the combination of the reference of Walt et al. with any of Felder et al., Chang et al. or Ravkin et al that suggest the use of first and second portions of different shape.”

(Office Action, p.23). Applicants note that the Examiner provides absolutely nothing to support this statement. Even if these references teach beads can be of different shapes – from one another – this does not teach first and second portions of a single bead which differ in shape. Each reference is addressed below.

2. Felder, Chang and Ravkin Do Not Teach Portions Of Different Shape

The Examiner cites Felder, Chang and Ravkin as allegedly teaching first and second portions of a sensing element having different shapes. However, Felder teaches merely bifunctional linkers having first and second portions – not sensing elements. A word search of Chang for “portion” reveals the term is not even used in the reference. A word search of Ravkin for “portion” reveals the term is used twice, but not in the context of first and second portions of different shapes. In sum, there is nothing in these three references that teaches this feature of Claim 76.

Without something in the references for support, the Examiner cannot make the argument. In this regard, the Examiner is asked to take note of the recent Supreme Court opinion which says that a specific showing by the Examiner is required:

Often, it will be necessary ... to look to interrelated teachings of multiple patents ... in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *To facilitate*

review, this analysis should be made explicit. See, *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) (“[R]ejections on obviousness grounds *cannot be sustained by mere conclusory statements*; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”).

KSR v. Teleflex, Slip Op No. 04-1350 (April 30, 2007). It is respectfully submitted that the analysis has NOT been made explicit and that the Examiner has merely made a conclusory statement without the necessary underpinning to support it. As such, the rejection of Claim 76 for obviousness cannot stand.

G. The Dependent Claims Are Not Obvious

The Examiner rejects Claim 103. However, Claim 103 is a dependent claim, i.e. dependent on Claim 50 which (as noted above) is not obvious. Since the independent claim is not obvious, the dependent claims are not obvious.

CONCLUSION

It is believed that the arguments and amendments render the claims allowable. Should the Examiner believe that a telephone interview would aid in the prosecution of this application Applicants encourage the Examiner to call the undersigned collect at (781) 828-9870.

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